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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/474,980

12/29/1999

Eugene M. Johnson

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3036

21888

7590

06/29/2004

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/474,980

Applicant(s)

JOHNSON ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 4/06/04 has been entered.
2. The rejection of claims 32-38 under 35 U.S.C. 112, first paragraph, for lack of written description is withdrawn due to the amendment of the claims.
3. The rejection of claims 32-38 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn due to the amendment of the claims.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Applicants' arguments filed 4/06/04 have been considered but are not found persuasive.
6. Claims 32-38 stand rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al (U.S. Patent 6,090,778), for the reasons made of record in Paper No: 17 (mailed 11/06/03), and as follows.

Applicants argue on page 4 of the response that "Johnson does not teach the persephin, as depicted in SEQ ID NO:221. Thus, Johnson cannot anticipate the claimed antibodies that react with SEQ ID NO:221." In contrast to Applicants' assertions, claim 38 still recites an

“oligopeptide amino acid sequence... conserved within the GDNF/neurturin/persephin family”, in which those sequences conserved between neurturin and GDNF reasonably define those “sequences... conserved within the GDNF/neurturin/persephin family”, by definition. Thus, Applicants’ arguments are not persuasive, because Johnson et al specifically teach antibodies directed to conserved regions within the “GDNF/neurturin family”, which reasonably would be identical to that currently claimed.

It is suggested that Applicants cancel claim 38 and consider making arguments related to stretches of nonconserved contiguous amino acid residues/epitopes, etc. unique to persephin, and/or present evidence for the lack of cross-reactivity between GDNF and neurturin antibodies with persephin.

In summary, Johnson et al. teach antibodies and a method of preparing antibodies to neurturin, which is a persephin/neurturin family member that inherently *comprise* “an oligopeptide that is part of the persephin polypeptide” (e.g., see Figure 15 of the instant application) at “amino acid sequences... conserved within the GDNF/neurturin/ persephin family” (i.e., column 27, lines 59-63; column 44; Figure 5; as it relates to claims 35-36 & 38), and therefore, inherently are “*capable of* reacting with a persephin polypeptide...” (i.e., as it relates to claims 32, 35-36 & 38). In that these shared epitopes are also reasonably “hydrophilic” (e.g., see column 27, line 55-58), the limitations of claim 37 are anticipated. In that ‘778 (columns 27-28) teach polyclonal antibodies, as well as monoclonal antibodies, which further reasonably are “*capable of* reacting with a persephin polypeptide as set forth in SEQ ID NO:221” at these regions conserved within the GDNF/neurturin family, as indicated in Figure 5

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of '778, and therefore, also are reasonably "conserved... [within the] GDNF/ neurturin/persephin family", the limitations of claims 32-34 are further met.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.



Robert C. Hayes, Ph.D.
June 24, 2004



GARY KUNZ
SUPERVISORY PATENT EXAMINER
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